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50. (Twice Amended) A device for treating a heart to induce ion channel remodeling, comprising a substrate having linked multiple electrode pairs consisting of two columns adapted to contact [for contacting] an epicardial surface of a heart and a[,] pacemaker for delivering periodic pacemaker electrical signals to the epicardial surface through said electrode pairs, to induce ion channel remodeling in the heart.

Remarks

Reconsideration and allowance in view of the amendments made and comments which follow are respectfully requested.

Claims 1-60 were pending. Claims 5, 9, 10, 12, 21, 24, 31, 34, 40, 43, 47, 48 and 50 are being amended. Claims 1-60 are still pending.

In the Office Action dated February 22, 2002 claims 1-60 were rejected under 35 U.S.C. 101 allegedly because the claimed invention is directed to non-statutory subject matter. The Examiner stated that specifically, claims 1(2), 5, 10-11, 12(2), 20(2), 24, 28-31, 39(2), 43, 47-49, 50(2), 58(2), 59(2) and 60(2) contain a phrase or phrases such as: "contacting ... pairs to an/the epicardial surface", "pacemaker to apply ... signals to the epicardial surface", "containing ... pairs to an epicardial vein", "containing ... pairs into an epicardial vein", "placing electrodes into heart ventricles", "having ... pairs ... for contacting an epicardial surface", "delivering ... signals to the epicardial surface", "columns for contacting and epicardial surface", "pacemaker for delivering ... signals to the epicardial surface", "strip containing... pairs to the epicardial surface" and "delivering ... signals to the epicardial surface" which amounts to inferential recitation of the body, which renders these claim non-statutory.

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The Examiner stated that, to address the understood intent of the applicant and avoid the 35 U.S.C. 101 rejections, as an example, the phrase "linked multiple electrode pairs adapted to be contacting the epicardial surface" is suggested to replace the phrase "contacting linked multiple electrode pairs to the epicardial surface".

In response to the rejection under 35 U.S.C. §101, applicant notes that some method claims were included in the rejection, and to this extent, the rejection is being traversed. Applicant believes that a method reciting steps of interacting with or treating the body does not render the method claim non-statutory because the invention recited is a method. Indeed, the step of interacting with or treating the body is needed to properly define the subject matter for which protection is being sought. With respect to the apparatus claims, applicant has amended claims 12, 31 and 50 as suggested by the Examiner.

The Examiner stated that the description portion of this application contains a list of references on page 46-52 which must be removed from the specification and included as an appendix. The Examiner stated that a reference to the newly added appendix should be included at the beginning of the specification. In response, applicant is not aware of any statute, regulation or MPEP section which prohibits listing references in a specification, and has followed this practice for many years in other applications without objection. Further, page 1 of the application incorporates these publications by reference, and applicant wishes to make sure that the issued patent includes this list, in hard copy and other electronic forms. Applicant respectfully requests reconsideration and withdrawal of this requirement.

The Examiner stated that on page 18, line 10, "hearing" should be --heart--. The specification is being amended to include this

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change.

The Examiner objected to the disclosure, stating that in claim 50, line 4, "and a, pacemaker" should be --and a pacemaker--. The specification is being amended to include this change.

The Examiner rejected claims 5, 9, 10, 21, 24, 34, 40, 43, 47 and 48 under 35 U.S.C. 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner stated that claims 5, 9, 10, 21, 24, 40, 43, 47 and 48 are dependent claims with the phrase "linked multiple electrode pairs", and the related independent claim also contains "linked multiple electrode pairs". The Examiner stated that if the "linked multiple electrode pairs" of the dependent claim are the same as the "linked multiple electrode pairs" of the independent claim, "linked multiple electrode pairs" in the dependent claims should be -- the linked multiple electrode pairs--.

In response to the rejection under 35 U.S.C. §112, second paragraph, claims 5, 9, 10, 21, 24, 34, 40, 43, 47 and 48 are being amended as suggested by the Examiner.

The Examiner stated that in claim 34, lines 1-2, "the at least two electrode pairs" allegedly lacks antecedent basis. This claim is being amended to change "at least two" to --linked multiple--

The Examiner rejected claims 1, 9-11, 20, 28-30, 39, and 47-49 under 35 U.S.C. 102(e) as being allegedly anticipated by Prutchi (US 6152882). The Examiner stated that Prutchi discloses an apparatus and method for chronic measurement of monophasic action potentials (citing abstract and 16, 11 19-44). The Examiner stated that the embodiment of this invention shown in figure 22B

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is an implantable pacing device for chronically recording the MAP signals and determining the duration of the refractory periods (citing to 29, 11 51-56). The Examiner stated that the device includes an implantable housing (352), a lead or catheter (351) with a plurality of electrodes for sensing, pacing and electroporating (citing to c. 29, 11. 57-65), an electroporating unit (354), a controlled (362) and a pacing core (350). The Examiner stated that the device can determine and manage the effective refractory period of the cardiac tissue (citing to c 30 1.49 - c. 31, 120). The Examiner stated that the electroporating unit (354/30), containing a pulse generator (32), controllably applies electrical current pulses having a duration, shape, polarity and magnitude sufficient to cause reversible dielectric breakdown of the cell membranes (citing to c 17, 162-c 18, 15). The Examiner stated that the brief pulses are applied to prevent electrical uncoupling of the cell layers (citing to c 20, 11, 34-37). The Examiner stated that the lead can be a catheter (50) and electrodes (52 and 54) (citing to 19, 11 40-49) and the lead can be placed in the ventricle (citing to c 20, 11 16-23). The Examiner stated that an epicardial electrode, with holes for sewing the electrode to the heart, can be used with the invention (citing to c 20, 11 55-67). The Examiner stated that the electrode and lead is made of an electrically insulating biocompatible material (citing to c 20, 11 60-64). The Examiner stated that the plurality of electrodes on the catheter (figure 13) are arranged in paris (citing to c 23, 11 3-14). The Examiner stated that the geometric arrangement of the plurality of electrodes can vary depending on the application (citing to c 23, 11 26-30). The Examiner stated that each electrode can be controlled individually using multiplexing and switching circuits to enable multiple pairing and stimulation configurations (citing to c 23, 11 32-38). The Examiners stated that an electrode array, shown in figure 14, can be used with this invention (citing to c 23, 11 56-61).

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The Examiner stated that this invention relates to treating the heart using electrical excitation of the electrically excitable and electrically coupled cardiac muscle cells (citing to c 1, 11 12-27).

The Examiner stated that the heart can be treated by specifying electrical stimulation to alter the effective refractory period of the heart citing to c 2, 11 3-29), hence the device and apparatus disclosed by Prutchi treats the heart to alter the effective refractory period.

The Examiner stated that electrical stimulation of the cardiac tissue is believed to change the electrical conductivity properties of the gap-junctions that couple the cardiac muscle cells. The Examiner stated that changes in ion components may also play a role in the change in electrical conductivity ultimately modifying the current flowing between cells citing to (c 4, 1 63-c 5, 114). The Examiner stated that applicants reference, Lodish pp 640 and 641, states opening the Na⁺, K⁺ and Ca²⁺ (ion) channels are essential to conduction of an electrical impulse in a nerve cell. The Examiner stated that the device and apparatus disclosed by Prutchi treats the heart to remodel gap junctions and to induce ion channel remodeling.

The Examiner rejected claims 2, 4, 5, 12, 13, 15, 21, 23, 24, 31, 32, 34, 40, 42, 43, 50, 51, 53 and 58-60 under 35 U.S.C. 103(a) as being allegedly unpatentable over Prutchi (US 6152882) in view of Edwards et al. (US 5681308). The Examiner stated that, as discussed in paragraph 7 of this action, Prutchi discloses the claimed invention except for the 7cm x 1 cm (claims 4, 23, and 42) strip (claims 2, 13, 21, 32, 40 and 51) of electrode material having linked multiple electrode pairs, where the pair are arranged in two columns (claim 12, 31 and 50) with one electrode in each pair in one column and the other electrode in each pair in the other column (claim 5, 14, 24, 34, 43, 53 and 58-60).

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The Examiner stated that Edwards et al disclose an analogous mapping apparatus and teach that it is known to use a circuit (38) mounted on a membrane support (16) to serve as a cardiac electrode which provides columns of individually controlled treatment electrodes (34) which can be multiplexed to enable stimulation of electrode pairs (citing to figure 7 and c 7, 11 38-52). The Examiner stated that absent any teaching of criticality or unexpected results, it is understood the electrode can be configure as a 7 cm x 1 cm strip with only two columns of electrodes. The Examiner stated that the configuration change is an obvious change in shape based on the specific application. The Examiner stated that, therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus and method for chronic measurement of monophasic action potentials as taught by Prutchi, with the electrode as taught by Edwards et al. to provide a flat electrode with multiple electrode measurement and stimulation configurations so the cardiac tissue can be more effectively treated.

The Examiner rejected claim 3, 7-8, 14, 17-19, 22, 26-27, 33, 36-38, 41, 45-46, 52 and 55-57 under 35 U.S.C. 103(a) as being allegedly unpatentable over Prutchi (US 6152882) and Edwards et al. (5681308) in view of Dahl et al (US 5203348). The Examiner stated that, as discussed in paragraph 8 of this action, modified Prutchi discloses the claimed invention except for:

- the electrode strip of polyurethane (claims 3, 14, 22, 33, 41, and 52),
- the electrode comprised of platinum or consisting essentially of unalloyed platinum (claims 7-8, 17-18, 26-27, 36-37, 45-46 and 55-56), and

the electrode connected to an insulated stainless

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steel wire (claim 19, 39 and 57).

The Examiner stated that Dahl et al disclose an electrode and teaches that it is known to fabricate an electrode with a platinum or platinum alloy conductor or conductor with a stainless steel core (citing to c 5, 11 19-36), and a lead with a medical grade polyurethane sheath and a stainless steel coated conductor (citing to c 5, 11 23-38). The Examiner stated that, therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified apparatus and method for chronic measurement of monophasic action potentials as taught by Prutchi, with the materials of construction as taught by Dahl et al..

The Examiner stated that one have ordinary skill in the art would have been motivated to make such a modification in electrode to specify materials of construction that have proven electrical properties.

The Examiner rejected claims 6, 16, 25, 35, 44 and 54 under 35 U.S.C. 103(a) as being allegedly unpatentable over Prutchi (US 6152882) and Edwards (US 5681308) in view of Ideker (US 5873896). The Examiner stated that, as discussed in paragraph 8 of this action, modified Prutchi discloses the claimed invention except for the electrode pair being 2mm from each other and the electrode pairs being spaced at least 5 mm apart. The Examiner stated that Idecker teaches a cardiac device for reducing arrhythmias and teaches that it is known to use an electrode configuration of an elongate primary strip with a plurality of electrodes positioned at spaced intervals, e.g. 1-4 millimeters (citing to c 3, 11 2-4). The Examiner stated that, therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified apparatus and method for chronic measurement of monophasic action potentials as taught by Prutchi, with the electrode spacing as

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taught by Ideker to provide electrode spacing known to effectively reduce cardiac arrhythmias.

Applicant will next address the rejection of claims 1, 9-11, 20, 28-30, 39 and 47-49 as being allegedly anticipated by U.S. Patent No. 6,152,882 to Prutchi. The Prutchi reference is directed to a device used to record monophasic action potentials or similar electrical potentials either while the heart is in sinus rhythm or during stimulation via a variety of methods from a single site, which single site of stimulation and recording may be varied. Prutchi's intent is to record a signal or signals produced by the heart and to monitor this chronically as an indicator of electrophysiological status. Prutchi nowhere teaches or suggests pacing from multiple sites in a strip to modify the electrical function of the heart by remodeling gap junctional properties. In fact, Prutchi does not even mention gap junctions. The monophasic action potentials which Prutchi seeks to record do not reflect gap junctional activity and do not rely on gap junctions. Instead, the monophasic action potentials rely on other ion channels.

The Examiner has cited to the Prutchi reference starting at col. 17, line 60 which relates to an electroporating unit 30. There is no teaching that remodeling of any gap junction activity is intended or would occur, even inherently, by using this unit.

The Examiner has also cited to the Prutchi reference starting at col. 23, line 4, which discusses pairs of electrodes. There is no teaching that remodeling of any gap junction activity is intended or would occur, even inherently, by using this device. Even if gap junctions remodeling could be achieved by using the device in a way not disclosed, the remodeling would be asymmetrical which might well be arrhythmogenic instead of antiarrhythmic.

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The Examiner has cited to Prutchi starting at col. 29, line 51 and col. 30, line 46 which relates to an implantable pacemaker. However, there is no teaching or disclosure that gap junctions could be remodeled, at least without further essential information not disclosed and not shown to be within the knowledge and skill of one skilled in the art at the time the subject invention was made.

In summary Prutchi simply monitors monophasic action potentials with a recording devices and a single electrode, and nowhere teaches or suggests remodeling gap junctions by pacing with antiarrhythmic intent. Accordingly, Prutchi fails to teach or suggest, directly or inherently, applicant's invention in independent claims 1, 12, 20, 31, 39, 50, 58, 59, or 60.

The other rejections are based on the Prutchi reference in combination with another reference, and rely on the Prutchi reference as a primary reference. However, as discussed above, the Prutchi reference fails to teach or suggest any aspect of remodeling gap junctions, altering the refractory period in the heart, or inducing ion channel remodeling. The other references also fail to remedy the deficiencies of Prutchi in this respect. Therefore, these proposed combinations necessarily fail to teach or suggest the claims against which they were cited. Moreover, applicant urges that there is no teaching or suggestion in the prior art or otherwise of anything that would motivate one of ordinary skill in the art to combine the references as proposed by the Examiner.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invites the Examiner to telephone them at the number provided below.

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No fee is deemed necessary in connection with the filing of this Response. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.


Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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Sub E' D1
5. The method according to claim 1, wherein the step of contacting comprises contacting the linked multiple electrode pairs to the epicardial surface of the heart, wherein the linked multiple electrode pairs are arranged in two columns with one electrode in each pair in one column, and the other electrode in each pair in the other column.

E' D2
9. The method according to claim 1, wherein the step of contacting comprises sewing a substrate strip containing the linked multiple electrode pairs to the epicardial surface of the heart.

E' D3
10. The method according to claim 1, wherein the step of contacting comprises locating a transvenous catheter containing the linked multiple electrode pairs into an epicardial vein.

E' D4
12. A device for treating a heart to obtain gap junction remodeling, comprising a substrate having linked multiple electrode pairs consisting of two columns adapted to contact an epicardial surface of a heart and a pacemaker for delivering periodic pacemaker electrical signals to the epicardial surface through said electrode pairs, to remodel gap junctions in the heart.

E' D5
21. The method according to claim 20, wherein the step of contacting comprises contacting a strip electrode material having the linked multiple electrode pairs mounted thereon.

E' D6
24. The method according to claim 20, wherein the step of contacting comprises contacting the linked multiple electrode pairs to the epicardial surface of the heart, wherein the

E' D6 linked multiple electrode pairs are arranged in two columns with one electrode in each pair in one column, and the other electrode in each pair in the other column.

E' D7 31. A device for treating a heart to alter the effective refractory period, comprising a substrate having linked multiple electrode pairs consisting of two columns adapted to contact an epicardial surface of a heart and a pacemaker for delivering periodic pacemaker electrical signals to the epicardial surface through said electrode pairs, to alter the effective refractory period in the heart.

E' D8 34. The device according to claim 31, wherein the linked multiple electrode pairs are arranged in two columns with one electrode in each pair in one column, and the other electrode in each pair in the other column.

E' D9 40. The method according to claim 39, wherein the step of contacting comprises contacting a strip electrode material having the linked multiple electrode pairs mounted thereon.

E' D10 43. The method according to claim 39, wherein the step of contacting comprises contacting the linked multiple electrode pairs to the epicardial surface of the heart, wherein the linked multiple electrode pairs are arranged in two columns with one electrode in each pair in one column, and the other electrode in each pair in the other column.

E' D11 47. The method according to claim 39, wherein the step of contacting comprises sewing a substrate strip containing the linked multiple electrode pairs to the epicardial surface of the heart.

E' D12 48. The method according to claim 39, wherein the step of contacting comprises locating a transvenous catheter containing the linked multiple electrode pairs into an

E' D² epicardial vein.

E' D³ 50. A device for treating a heart to induce ion channel remodeling, comprising a substrate having linked multiple electrode pairs consisting of two columns adapted to contact an epicardial surface of a heart and a pacemaker for delivering periodic pacemaker electrical signals to the epicardial surface through said electrode pairs, to induce ion channel remodeling in the heart.